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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,473	11/13/2007	Xian-Ming Zeng	TEVE-124US	9501

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EXAMINER	
SINGH, RANDEEP	
ART UNIT	PAPER NUMBER
1615	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/594,473	ZENG ET AL.
	Examiner	Art Unit
	RANDEEP SINGH	1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 March 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) *11 and 12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)	
1) ☒ Notice of References Cited (PTO-892)	4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) ☐ Notice of Informal Patent Application
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/13/07, 11/24/09*.	6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Response to Restriction/Election filed 3/14/11 and the Information Disclosure Statements filed on 11/13/07 and 11/24/09 are acknowledged.

Applicants' election without traverse of Group I (claims 1-10) in the reply filed 3/14/11 is acknowledged. Claims 11 and 12 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 1-10 are pending in this action. Claims 1-10 have been examined in this action. Claims 11 and 12 have been withdrawn (non-elected invention). Claims 1-10 are rejected.

Information Disclosure Statement

The information disclosure statements submitted on 11/13/07 and 11/24/09 are acknowledged. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly the information disclosure statements are being considered by the examiner.

Claim Objections

Claim 6 and 9 are objected to under 37 CFR 1.75(c) as being in improper dependent form because they are multiple dependent claims referring back to other

multiple dependent claims. See MPEP § 608.01(n). Accordingly, claims 6 and 9 have not been further treated on the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5, 7, 8, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Walz et al. (hereinafter "Walz").

Regarding claim 1, Walz discloses a process for preparing a medicament comprising combining a pharmaceutically active ingredient (tiotropium bromide monohydrate) with an excipient (lactose monohydrate) in a mixing container (see paragraphs [0063] – [0064]). The process disclosed in Walz also includes passing the active ingredient/excipient mixture through a sieve with a mesh size of 0.1 to 2 mm (see paragraph [0020]) and then mixing the active ingredient/excipient mixture in a gravity mixer at 900 rpm (see paragraph [0065]). The active substances of Walz preferably

have an average particle size of 2 to 5 µm, and the excipients preferably have an average particle size of 20 to 30 µm (see paragraph [0013]).

Regarding claim 2, Walz discloses inhalable powders characterized by an exceptional degree of homogeneity (92% or greater) (see paragraph [0029]). Walz is silent as to whether the pharmaceutically active ingredient is dispersed homogeneously in the pharmaceutically acceptable particulate carrier such that drug recovery from each of the plurality of samples taken from the medicament has a relative standard deviation from the mean of less than or equal to 5%. However, the examiner notes that "inhalable powders characterized by an exceptional degree of homogeneity", as recited by Walz, would necessarily have sufficient homogeneity such that drug recovery from each of a plurality of samples taken from the medicament has a relative standard deviation from the mean of less than or equal to 5%. Regarding claims 3-5, Walz discloses passing an active substance/excipient mixture through a sieve with a mesh size of 0.1 to 2 mm (see paragraph [0020]).

Regarding claims 7-8, Walz discloses corticosteroids as pharmaceutically active ingredients. Budesonide is mentioned as a preferred active ingredient (see paragraph [0025]).

Regarding claim 10, Walz discloses lactose monohydrate as a preferred excipient (see paragraph [0028]).

Claims 1-5, 7, 8, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Bystrom et al. (hereinafter "Bystrom").

Regarding claim 1, Bystrom discloses a process for preparing a medicament comprising combining a biologically active component and a lipid (excipient) in a solvent, freezing the mixture to obtain a crystalline solvent matrix, and evaporating the frozen solvent to attain a powder (see column 5, lines 3-23). The processes disclosed in Bystrom further include passing the powder through a sieve or deagglomerating the powder in an inhaler to obtain particles within a respirable particle size range (see column 5, lines 21-23 and column 5, lines 56-63). The powder of Bystrom consists of particles having a diameter of less than 10 microns (see column 4, lines 20-24). Preferably, at least 90% of the powder consists of particles within the desired size range (see column 4, lines 25-30).

Regarding claim 2, Bystrom discloses a homogeneous molecular mixture of a biologically active component and a lipid (excipient) (see column 2, lines 35-38). Bystrom is silent as to whether the pharmaceutically active ingredient is dispersed homogeneously in the pharmaceutically acceptable particulate carrier such that drug recovery from each of the plurality of samples taken from the medicament has a relative standard deviation from the mean of less than or equal to 5%. However, the examiner notes that a "homogeneous molecular mixture of a biologically active component and a lipid", as recited by Bystrom, would necessarily have sufficient homogeneity such that drug recovery from each of a plurality of samples taken from the medicament has a relative standard deviation from the mean of less than or equal to 5%.

Regarding claims 3-5, the powder of Bystrom, having a diameter of less than 10 microns (see column 4, lines 20-24), is capable of passing through a sieve having a mesh of 50-3000 μm.

Regarding claims 7-8, Bystrom discloses glucocorticosteroids as pharmaceutically active ingredients. Budesonide is mentioned as a preferred active ingredient (see column 3, line 53).

Regarding claim 10, Bystrom discloses lactose monohydrate as a preferred excipient (see column 4, lines 40-41).

Claims 1-5, 7 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Lizio et al. (hereinafter "Lizio").

Regarding claim 1, Lizio discloses a process for preparing a medicament comprising combining a pharmaceutically active ingredient (budesonide) with a pharmaceutically acceptable particulate carrier (CapsuLac). This premixture is sieved through a stainless steel sieve having a slot width of 0.1 to 0.5 mm (see paragraph [0013]) and then mixed in a turbula (centrifugal mixer), producing a powder suitable for inhalation (see paragraph [0056]). In an embodiment, 90% of the particles produced by this method are smaller than 4.9 μm (see paragraph [0024]).

Regarding claim 2, Lizio discloses homogenous mixtures of lactose with, for example, formoterol (see paragraph [0040]). Lizio is silent as to whether the pharmaceutically active ingredient is dispersed homogeneously in the pharmaceutically acceptable particulate carrier such that drug recovery from each of the plurality of

samples taken from the medicament has a relative standard deviation from the mean of less than or equal to 5%. However, the examiner notes that "homogenous mixtures", as recited by Lizio, would necessarily have sufficient homogeneity such that drug recovery from each of a plurality of samples taken from the medicament has a relative standard deviation from the mean of less than or equal to 5%.

Regarding claims 3-5, Lizio discloses the use of sieves having a slot width of 0.1 to 0.5 mm (see paragraph [0013]).

Regarding claims 7-8, Lizio discloses bronchodilators as pharmaceutically active ingredients (see paragraph [0018]). Budesonide is mentioned as an example active ingredient (see paragraph [0056]).

Claims 1 and 3-5 are rejected under 35 U.S.C. 102(e) as being anticipated by Backstrom et al. (hereinafter "Backstrom").

Regarding claim 1, Backstrom discloses a process for preparing a medicament comprising combining a pharmaceutically active ingredient (insulin) with a pharmaceutically acceptable particulate carrier (lactose). The process disclosed by Backstrom further includes passing the mixture through a 0.5 mm sieve and then micronizing the mixture in a jet mill to particles of about 2 microns in diameter (see column 10, Examples 1 and 2). In embodiments, at least 50%, preferably at least 90%, of the particles produced by the process of Backstrom have a diameter of up to 10 microns (see column 3, lines 30-35).

Regarding claims 3-5, Backstrom discloses the use of sieves having a slot width of 0.5 mm (see column 10, Examples 1 and 2).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Walz et al. (hereinafter "Walz").

As discussed above, Walz discloses inhalable powders characterized by an exceptional degree of homogeneity (92% or greater). Walz is silent as to whether the pharmaceutically active ingredient is dispersed homogeneously in the pharmaceutically acceptable particulate carrier such that drug recovery from each of the plurality of samples taken from the medicament has a relative standard deviation from the mean of less than or equal to 5%.

Although "inhalable powders characterized by an exceptional degree of homogeneity", as recited by Walz, would necessarily have sufficient homogeneity such that drug recovery from each of a plurality of samples taken from the medicament has a relative standard deviation from the mean of less than or equal to 5%, in the event that this limitation is not apparent in the teachings of Walz, it would be well within the ordinary level of skill in the art to arrive at the desired degree of homogeneity. With regards to the limitation reciting the standard deviation from the mean, the examiner notes that generally, specific values will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating that such values are critical.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bystrom et al. (hereinafter "Bystrom").

Bystrom discloses a homogeneous molecular mixture of a biologically active component and a lipid (excipient). Bystrom is silent as to whether the pharmaceutically active ingredient is dispersed homogeneously in the pharmaceutically acceptable particulate carrier such that drug recovery from each of the plurality of samples taken from the medicament has a relative standard deviation from the mean of less than or equal to 5%.

Although a "homogeneous molecular mixture of a biologically active component and a lipid", as recited by Bystrom, would necessarily have sufficient homogeneity such that drug recovery from each of a plurality of samples taken from the medicament has a relative standard deviation from the mean of less than or equal to 5%, in the event that this limitation is not apparent in the teachings of Bystrom, it would be well within the ordinary level of skill in the art to arrive at the desired degree of homogeneity. With regards to the limitation reciting the standard deviation from the mean, the examiner notes that generally, specific values will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating that such values are critical.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lizio et al. (hereinafter "Lizio").

As discussed above, Lizio discloses homogenous mixtures of lactose with, for example, formoterol. Lizio is silent as to whether the pharmaceutically active ingredient is dispersed homogeneously in the pharmaceutically acceptable particulate carrier such

that drug recovery from each of the plurality of samples taken from the medicament has a relative standard deviation from the mean of less than or equal to 5%.

Although "homogenous mixtures of lactose with, for example, formoterol", as recited by Lizio, would necessarily have sufficient homogeneity such that drug recovery from each of a plurality of samples taken from the medicament has a relative standard deviation from the mean of less than or equal to 5%, in the event that this limitation is not apparent in the teachings of Lizio, it would be well within the ordinary level of skill in the art to arrive at the desired degree of homogeneity. With regards to the limitation reciting the standard deviation from the mean, the examiner notes that generally, specific values will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating that such values are critical.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RANDEEP SINGH whose telephone number is (571)270-3881. The examiner can normally be reached on Monday-Friday 10:00-6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571)272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Randeep Singh/
Examiner, Art Unit 1615

/Robert A. Wax/
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